DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Washington DC 20204

WARNING LETTER
ONPLDS- 04-00

AUG 15 2000

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Lee Labrada
President
Labrada Bodybuilding Nutrition, Inc.
403 Century Plaza Drive
Suite 440
Houston, Texas 77073

Dear Mr. Labrada:

The Food and Drug Administration (FDA) has reviewed the label for your Lean Body Hi-Protein Meal Replacement Bar. Our review reveals that this label causes the above product to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

This product is misbranded because the label bears the claim "LOW CARBOHYDRATE" which is a nutrient content claim that is not authorized by regulation or the Act (21 U.S.C. 403(r)(1)(A)).

The above violation is not meant to be an all inclusive list of deficiencies on your labels. It is your responsibility to assure that all of your products are labeled in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

We have the following additional comments:

The regulations for declaring nutrition information contained in Title 21, Code of Federal Regulations (21 CFR 101.9) does not provide for the declaration of "Non-sugar alcohol" as part of the nutrition format.

The statement "Due to limitations of the bar-coating technology, the fat content of bars may vary slightly" should not appear on this label. A food is misbranded if the level of fat in the product is more than 120 percent of the value declared on the label.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken or plan to take to correct the noted violations. Copies of revised labels for the product should be submitted. If corrective actions cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

You should direct your written reply to me at: the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-810), 200 C Street, S.W., Washington, D.C. 20204.

Sincerely yours,

/s/

John B. Foret
Director
Division of Compliance
and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition